UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

STEVE HUTSON,
Plaintiff,

v.

Case No. 2:13-cv-895
CHIEF JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Elizabeth Preston Deavers

COVIDIEN HOLDING, INC., COVIDIEN LP, and PATTERSON DENTAL SUPPLY, INC.,
Defendants.

OPINION & ORDER

This matter is before the Court on Defendants Covidien Holding, Inc., Covidien, LP, and Patterson Dental Supply, Inc.'s ("Covidien") Motion to Exclude or Limit the Testimony of Plaintiff's Expert (ECF No. 36) and Motion for Summary Judgment (ECF No. 34). For the reasons that follow, the motions are **GRANTED**.

I. BACKGROUND

Plaintiff Steve Huston filed this product liability action against Covidien following a dental procedure gone awry. In November 2011, Hutson went to his dentist, Dr. David Merino, for a root canal. (Merino Dep. at 19-20; ECF No. 35-1.) As part of the procedure, Dr. Merino injected a needle into Hutson's gum to administer anesthesia. (*Id.* at 38-40.) Covidien's needle box warned "not [to] bend or alter needle shaft prior to use . . . ." The box further warned against "insert[ing] needle shaft all the way to the hub as needle breakage and possible injury may result." Nevertheless, Dr. Merino bent the needle 10-20 degrees at the hub, and then injected the entire length of the needle into Hutson's gum. (*Id.* at 20-24, 43, 54-57, 94.) A few minutes later, he repeated the procedure, injecting more anesthesia into Huston's gum using the same needle. (*Id.* at 38-39, 41.) When Dr. Merino attempted to remove the needle from

Hutson's mouth, it broke at the hub from the syringe and lodged in Hutson's gum tissue with no portion sticking out. (*Id.* at 48-50.) Eventually, an oral surgeon removed the needle.

Hutson then sued Covidien, alleging that a manufacturing defect caused the needle to break during his root canal and thus the company is strictly liable. Covidien moved for summary judgment (ECF No. 34) and to exclude or limit the testimony of Huston's expert, Alan Lipschultz (ECF No. 36).

II. ANALYSIS

The Court first addresses Covidien's attempt to exclude the testimony from Hutson's expert. Neither party asked for a *Daubert* hearing. Whether or not to hold such a hearing falls within this Court's discretion. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). The parties have fully briefed the issue and have field the relevant reports and deposition testimony. Because the record is fully developed, no such hearing is necessary. *See Iams Co. v. Nutro Products, Inc.*, No. 3:00-CV-566, 2004 WL 5831566, at *2 (S.D. Ohio Aug. 23, 2004) (denying hearing where record was fully developed and argument for hearing was only expert "would be more persuasive in person than on paper"); *see also Hometown Folks, LLC v. S&B Wilson, Inc.*, No. 1:06-CV-81, 2007 WL 4618445, at *3 (E.D. Tenn. Nov. 9, 2007) ("When a Court has an adequate basis on which to determine the reliability of a witness's testimony, it need not hold a *Daubert* hearing."). After addressing Covidien's *Daubert* motion, the Court turns to Covidien's Motion for Summary Judgment (ECF No. 34).

A. Motion to Exclude Hutson's Expert

Alan Lipschultz, a professional engineer and the only expert offered by Hutson, describes his "area of experience and expertise [as] Clinical Engineering, which is the applied application of the engineering discipline to all aspects of technology used in the clinical setting."

(Lipschultz Report at 2; ECF No. 35-3.) Hutson wants Lipschultz to "provide certain testimony" on "two core opinions." First, to a reasonable degree of engineering certainty, the subject needle had a manufacturing defect and should not have broken during Hutson's procedure. And second, there are four potential causes as to why the subject needle broke, three of which involve a manufacturing defect, but there is not enough data from the subject needle to rank the likelihood of the causes. (Resp. at 4; ECF No. 38.)

Lipschultz's opinions rest in part on a report written by two metallurgists. These metallurgists performed two studies with Covidien needles. The first examined the subject needle used by Dr. Merino that lodged in Hutson's gum. According to Lipschultz, the analysis was "substantially limited due to a foreign matter deposit on" the fracture surfaces, making "a complete analysis inconclusive." (Lipschultz Dep. at 62-63.) The second involved placing exemplar needles in a mechanical pencil and then preforming a three-point bend test and a right angle bend at the hub. (*Id.* at 173.) According to Hutson, the exemplar needles did not break or fracture despite "far more intense pressure than Dr. Merino had applied," demonstrating that needle used for Hutson's procedure "was more than likely defective." (Resp. at 7.) Hutson offers neither metallurgist as an expert, but Lipschultz observed some of their tests, "reviewed their report[,] and concur[ed] with its findings." (Lipschultz Report at 2.)

Covidien seeks to exclude both of Lipschultz's opinions, arguing that they are unreliable and not relevant in this case. Pursuant to Federal Rules of Evidence 702, "if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise . . . ." This Court has a "general gatekeeping [or screening] obligation . . . to exclude from trial expert

testimony that is unreliable and irrelevant." *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 792 (6th Cir. 2002) (internal quotation marks omitted).

Reliability hinges on whether the reasoning or methodology underlying the testimony is scientifically valid. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993). The expert must ground his or her testimony in the methods and procedures of science and must entail more than unsupported speculation or subjective belief. *Id.* Hutson bears the burden to prove by a preponderance of the evidence that the testimony is reliable. *Wellman v. Norfolk & Western Railway Co.*, 98 F. Supp. 2d 919, 923 (S.D. Ohio 2000) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994)). *Daubert* outlines factors to help determine reliability: "testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community." *United States v. Langan*, 263 F.3d 613, 621 (6th Cir. 2001) (citing *Daubert*, 509 U.S. at 593-94). This inquiry is "flexible," however, and *Daubert*'s factors "do *not* constitute a definitive checklist or test." *Kumho Tire Co*, 526 U.S. at 150 (citation and internal quotation marks omitted).

Covidien attacks the reliability of the exemplar-needle testing, highlighting that no attempt was made to replicate what occurred in Hutson's mouth. (Lipschultz Dep. at 88.) Unlike the procedure that Dr. Merino performed, the exemplar needles were not attached to a syringe and anesthetic was not affixed to the needle during testing. Instead, the metallurgists, with Lipschultz watching, stuck exemplar needles into a mechanical pencil and bent them.

Daubert's factors caution against relying on this method. It has never been tested, published, or subject to peer review. No written protocol controlled this approach. (Lipschultz Dep. at 79-80.) The procedure has no known or potential error rate. And aside from calling the

metallurgists' tests "standard," Hutson offers no explanation as to how this technique is generally accepted in the relevant scientific community.

Lipschultz's lack of relevant experience similarly paints this method as unreliable. *See Kumho Tire Co.*, 526 U.S. at 150 ("[T]he relevant reliability concerns may focus upon personal knowledge or experience."). Though Lipschultz states that he has been "called upon to investigate medical device incidents involving a broad variety of medical devices" (Lipschultz Report at 3), he highlights no experience working with needles. And, he testified that he has never performed a failure analysis on stainless steel. (Lipschultz Dep. at 33-34, 159.)

Hutson tries to justify the method used, asserting that the testing was intended to "recreate a fracture of the needle at the junction of the hub so that we would have a *comparison* surface to compare to . . . in addition to what kind of force would be necessary and what kind of bending." (Resp. at 7 (quoting Lipschultz Dep. at 86-87).) Though Hutson calls the mechanical-pencil experiment a "worst case" scenario because the metallurgists applied more pressure on the needle than Dr. Merino (Resp. at 8), nothing indicates that one can appropriately compare a needle bent while held by a mechanical pencil to a needle bent and then inserted twice into gum tissue during a nerve block procedure. Lipschultz recognized that the inside of a mechanical pencil "is definitely not the same as gum tissue" and acknowledged that he is "only vaguely" aware of how a dentist performs the type of procedure that Hutson underwent. (Lipschultz Dep. at 84-85, 173.) Moreover, no photographs exist comparing the subject and exemplar needles side-by-side. (Lipschultz Dep. at 140). And even if he could draw a comparison, Lipschultz stated at his deposition that analysis of the subject needle was "substantially limited due to a foreign matter deposit" on the fracture surface that made "a complete analysis inconclusive." (Lipschultz Dep. at 62-63.) Hutson insists that the examination nevertheless was "able to yield

valuable data as documented in Mr. Lipschultz's report." (Resp. at 11.) But he declines to elaborate and a review of the report similarly reveals no clues. Thus, Lipschultz employed an unreliable method in determining whether a defect existed. *See Phelan v. Synthes (U.S.A.)*, 35 F. App'x 102, 107 (4th Cir. 2002) (per curiam) (holding opinion not supported by reliable methodology where opinion "was based largely on extrapolation from a simple principle of engineering without quantitative or otherwise specific examination of the properties" of the allegedly defective nail).

Lipschultz's attempt to link the alleged manufacturing defect to the needle fracturing in Hutson's gum is based on the same unreliable method. His comparison lacks critical points such as how likely the needle would fail in Dr. Merino's application or the extent of stress or force that would need to be placed on the needle in Dr. Merino's procedure to fracture. And, Lipschultz does not identify how the needle was defective. While he narrows the cause of the fracture to four possibilities, he could not eliminate the prospect that Dr. Merino overloaded the needle with pressure during the root canal. In fact, he acknowledged that he lacked the data to rank the likelihood of this non-defective reason relative to the three defect-related possibilities. (Lipschultz Report at 6; ECF No. 35-3; Lipschultz Dep. at 159-60.) *Cf. Knotts v. Black & Decker, Inc.*, 204 F. Supp. 2d 1029, 1047 (N.D. Ohio 2002) ("The trier of fact must be presented with the probability as to the cause of the plaintiff's injuries and not a mere possibility."). Thus, Lipschultz's proffered testimony on the link between the alleged defect and the fracture is similarly unreliable. *See Phelan*, 35 F. App'x at 107 (excluding expert opinion that attempted to link alleged dangerous condition of nail to failure of nail in plaintiff's case where expert did not eliminate equally plausible causes for nail's breaking and did not testify regarding likelihood of nail failure or identify the extent of force placed on the nail during use).

True, Lipschultz consulted two metallurgists who conducted the tests and authored a report summarizing the subject needle exam, the exemplar needle testing, and the scanning electron microscope ("SEM") photographs of the subject and exemplar needles. But Hutson did not offer these metallurgists as experts. And as outlined above, the methods used by the metallurgists are not reliable here. In any event, "[a]n expert must make some findings and not merely regurgitate another expert's opinion." *Buck v. Ford Motor Co.*, 810 F. Supp. 2d 815, 844 (N.D. Ohio 2011); *see also Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002) ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty. That would not be responsible science."). Lipschultz's report states that it "contains the fracture analysis report of" the metallurgists, that he "reviewed [it] and concurs[s] with its findings," and that the "subject needle fracture resulted from one or more of the stainless steel failure mechanisms listed in [it]." Hutson and Lipschultz decline to explain how this is anything but a regurgitation of the metallurgists' findings. Neither explains how Lipschultz questioned and verified the metallurgists' data. Indeed, he did not witness all of the tests and conducted no tests on the subject needle himself. Moreover, he is not qualified to interpret the SEM photographs of the metal components taken by the metallurgists. (Lipschultz Dep. at 131, 133-34, 157; *see also* Resp. at 4.) Thus, Hutson has not demonstrated that Lipschultz reasonably relied on the metallurgists. *See Dura Automotive Sys.*, 285 F.3d at 615 (excluding proffered expert who relied on non-testifying experts when he lacked ability to assess underlying techniques that formed opinion); *see also Newell Rubbermaid, Inc. v. Raymond Corp.*, No. 5:08-CV-2632, 2010 WL 2643417, at *6 (N.D. Ohio July 1, 2010) *aff'd*, 676 F.3d 521 (6th Cir. 2012) (holding proffered expert's testimony not reliable in part because he did not question or verify data relied on and did not conduct any tests).

The Court **GRANTS** Covidien's Motion to Exclude the Testimony of Plaintiff's Expert (ECF No. 36).

B. Motion for Summary Judgment

With this in mind, the Court turns to Covidien's Motion for Summary Judgment (ECF No. 34). Summary judgment is appropriate if "there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In reviewing Covidien's motion for summary judgment, this Court must "view all facts and any inferences in the light most favorable" to Hutson, the nonmoving party. *Risch v. Royal Oak Police Dep't*, 581 F.3d 383, 390 (6th Cir. 2009); *see also Matushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). A motion for summary judgment should be denied if "there is a genuine need for trial," which turns on "whether the evidence is such that a reasonable jury could return a verdict for the plaintiff." *Weigel v. Baptist Hosp. of E. Tenn.*, 302 F.3d 367, 375 (6th Cir. 2002). Once "a motion for summary judgment is properly made and supported, an opposing party may not rely merely on allegations or denials in its own pleading." *Viergutz v. Lucent Technologies, Inc.*, 375 F. App'x. 482, 485 (6th Cir. 2010). Instead, the party opposing summary judgment "must—by affidavits or as otherwise provided in this rule—set out specific facts showing a genuine need for trial." *Id.*

Covidien presses that Hutson cannot prove that the subject needle used by Dr. Merino was defective, a necessary element of his product liability claim. *See Smitley v. Nissan N. Am., Inc.*, No. 2:09-CV-148, 2010 WL 3027915, at *2 (S.D. Ohio Aug. 2, 2010) (citing Ohio Rev. Code § 2307.73). "A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula,

or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards." Ohio Rev. Code § 2307.74.

To prove defect, Hutson points to Lipschultz's testimony that a manufacturing defect existed. Lipschultz's "basis is two-fold." First, he relies on the exemplar-needle testing where the needles would not fracture after two 90-degree bends at the hub. But because this testimony is unreliable for the reasons stated in Section II.A., it has no bearing at the summary judgment stage. Second, he points to Covidien's testing protocols that require the needle withstand bending at a 60-degree angle for 20 cycles without fracturing, which is more than Dr. Merino bent the needle. But this assessment makes no effort to take into account what happened after the needle's manufacture, such as its use in Hutson's nerve block procedure. And, Lipschultz could not identify how the needle was defective. He offers no reliable science for support and declined to test his hypothesis in any meaningful way. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."); *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996) ("Under the regime of *Daubert* . . ., a district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist."). Therefore, Lipschultz cannot create a genuine issue as to the existence of a manufacturing defect by pointing to Covidien's standard. *See Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010) ("Because the 'knowledge' requirement of Rule 702 requires 'more than subjective belief or unsupported speculation,' . . . the testimony should have been excluded.") (quoting *Daubert*, 509 U.S. at 590).

Dr. Merino's testimony similarly falls short of the mark. At his deposition, he stated that he "knew that there was something wrong with those needles" and that within days after

Hutson's procedure, a needle broke on another patient. (Merino Dep. at 86, 92.) But Dr. Merino never testified that that the subject needle had a manufacturing defect. Indeed, Dr. Merino testified that he had no opinion as to whether the subject needle deviated from Covidien's specifications because he had no knowledge of those specifications. (*Id.* at 15.) True, he testified that the needle deviated in a material way from identical Covidien needles because he never had this problem before. (*Id.* at 15.) But when asked "[h]ow did the needle deviate in a material way from identical needles," he responded "I don't know." (*Id.* at 16.) In fact, Merino at one point blamed the needle's alleged defects on someone tampering with them. (*Id.* at 86). Dr. Merino's deposition testimony does not raise a genuine issue as to whether the subject needle was defective when it left Covidien's control. The Court therefore **GRANTS** Covidien's Motion for Summary Judgment. (ECF No. 34.)

III. CONCLUSION

Covidien's Motion to Exclude or Limit the Testimony of Plaintiff's Expert, Alan Lipschultz (ECF No. 36) and Motion for Summary Judgment (ECF No. 34) are **GRANTED**.

IT IS SO ORDERED.

6-30-2015
DATE

EDMUND A. SARGUS, JR.
CHIEF UNITED STATES DISTRICT JUDGE